IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE AG, ALCON, INC. and ALCON MANUFACTURING, LTD. Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	Civil Action No. 06-234 (SLR) **PUBLIC REDACTED VERSION**

DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S
ANSWERING POST-TRIAL BRIEF
ON TEVA'S NONINFRINGEMENT OF CLAIM 1 OF THE '830 PATENT

May 22, 2008

BAYARD, P.A.

Richard D. Kirk (#0922)
Ashley B. Stitzer (#3891)
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899-5130
rkirk@bayardfirm.com
astitzer@bayardfirm.com
(302) 655-5000
Counsel for Defendant,
TEVA PHARMACEUTICALS USA, INC.

OF COUNSEL:

Bruce M. Gagala
M. Daniel Hefner
Douglas A. Robinson
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601

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SUMMARY OF ARGUMENT

The specification of the '830 patent defines the claim term "moxifloxacin" in express definitional format. Alcon admits that Teva's proposed ophthalmic solution, as defined in ANDA No. 78-073, does not include "moxifloxacin." Therefore, Teva does not infringe claim 1 of the '830 patent, the only claim asserted by Alcon. Also, Teva's product includes the S,S enantiomer of moxifloxacin hydrochloride, and not the structure defined in the '830 patent.

Alcon's proposed construction of "moxifloxacin" would require the Court to impermissibly ignore the express definition of "moxifloxacin" in the patent, and instead rely only on extrinsic evidence to revise and rewrite the patent. Not only is a rewrite directly contrary to appellate precedent, the revisionist claim construction Alcon seeks would also undermine the public policy underlying the "notice function" of patents, which prevents patentees from changing the meaning of claim terms after their patents' issuance, and which allows the public to know what is claimed.

Alcon's entire position on claim construction is a thinly-veiled attempt at an end-run around the statutory procedure for correction established by Congress. Alcon's ploy to achieve through claim construction what it cannot through statutory procedures is improper and should be disallowed.

ARGUMENT

Patent infringement occurs when an accused product includes all of the elements of a claim. *See, e.g., Engel Indus., Inc. v. Lockformer Co.*, 96 F.3d 1398, 1405 (Fed. Cir. 1996). The infringement analysis is a two-step process. *Elbex Video, Ltd. v. Sensormatic Elec. Corp.*, 508 F.3d 1366, 1370 (Fed. Cir. 2007). First, claim terms are construed. *Id.* Second, the construed claims are compared to the accused product. *Id.* In this case, the question of infringement collapses into the question of the construction of the term "moxifloxacin" in claim 1 of the '830

patent, the only claim asserted by Alcon to be infringed by Teva's proposed ophthalmic solution pursuant to Teva's ANDA No. 78-073.

I. Teva's Proposed Claim Construction Of Moxifloxacin Is The Only Proposed Construction That Is Consistent With The Intrinsic Evidence As A Whole

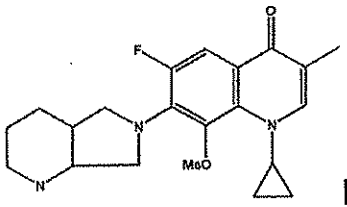
A. "Moxifloxacin" Is Expressly Defined In The '830 Patent

When a patent's specification contains a special definition of a claim term, the patent's definition (or "lexicography") governs with respect to claim construction. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005) (*en banc*). This is so even if the patent's definition flies in the face of an accepted meaning for the claim term, or even if it leads to nonsensical or inoperable claims. *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1361 (Fed. Cir. 2007); *Chef America Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374–75 (Fed. Cir. 2004). Simply put, if a patents' "specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of the term." *Sinorgchem Co. v. ITC*, 511 F.3d 1132, 1138 (Fed. Cir. 2007) (citation omitted).

The question of whether a patentee has acted as his own lexicographer is addressed objectively, from the perspective of the public. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004). The intent of the drafter is entirely immaterial. *Id.* Rather, "a patent must be interpreted 'as written, not as the patentees wish they had written it.'" *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 520 F.3d 1358, 1362 (Fed. Cir. 2008) (quoting *Chef America*, 358 F.3d at 1374).

Indicia in a patent's specification, such as using definitional words like "is" following the term-in-question, provide evidence that the patent has expressly defined the term. *Sinorgchem*, 511 F.3d at 1136; *Abbott Labs. v. Novopharm Ltd.*, 323 F.3d 1324, 1330 (Fed. Cir. 2003). Here, the patentee defined the claim term "moxifloxacin" in express definitional format. The term

"moxifloxacin" is followed by the word "has," providing a definition of the claim term without ambiguity. The '830 patent explicitly states: "Moxifloxacin has the following structure:



[(S)]"

(PTX 5, col. 3, ll. 36–48). Because Alcon's patent unequivocally states that the compound has structure (S) "there is no need to search further for the meaning of the term" "moxifloxacin." *Sinorgchem*, 511 F.3d at 11138. Moreover, structure (S) does not show the stereochemistry of the S,S enantiomer. The patent's express definitional language is the only correct construction of the term "moxifloxacin." *See, e.g., Phillips*, 415 F.3d at 1316; *Honeywell*, 493 F.3d at 1361–62. Accordingly, the cases relied on by Alcon (AB, p. 9[1]) are inapposite and unconvincing here.

B. Teva's Proposed Claim Construction Of "Moxifloxacin" Is Consistent With The '830 Patent's Specification As A Whole

Alcon insinuates that Teva fails to take into account the specification as a whole (AB, p. 10–13). This is misplaced; in fact, Teva's is the only proposed construction that is consistent with the specification, the primary source for construing the claims. *Phillips*, 415 F.3d at 1315.

The specification states explicitly that the "invention is based on the use of a potent *new class* of antibiotics...." PTX 5, col. 2, ll. 5–6 (emphasis added). However, in 1998, there was nothing new about quinolones as a "class" of antibiotics, as even Alcon admits (AB, p. 2), and as Dr. Taylor (one of Alcon's experts) also acknowledged. Tr. 100:5–101:22. Moreover, Dr. Taylor did not deny that the chemical of structure (S) would represent a new "class" of antibacterials; rather, he admitted that his opinion that the chemical of structure (S) would not

[1] "AB" (Alcon's Brief) refers to Plaintiff's Post-Trial Brief On Infringement (D.I. 93).

have antibacterial activity was based entirely on supposition, and not on any actual data. Tr. 113:24–114:17. The principles in *Daubert v. Merrill Dow Pharm., Inc.*, 509 U.S. 579 (1993) dictate that his unsupported opinion should be severely discounted.

Alcon also contends that the discussion in the '830 patent of quinolone antibiotics creates a context for the patent. AB, p. 10–12. This argument, however, brushes aside the undisputed fact that the ***only*** discussion of quinolone compounds appears in the "Background of the Invention" (PTX 5, col. 1, l. 13–col. 2, l. 3), which is merely a discussion of the prior art. Thus, after explaining that the prior art included the use of quinolones to treat ophthalmic infections, the '830 patent states:

> despite the general efficacy of the ophthalmic quinolone therapies currently available, there is a ***need*** for improved compositions and methods of treatment ***based on the use of antibiotics that are more effective than existing antibiotics*** against key ophthalmic pathogens, and less prone to the development of resistance by those pathogens.

PTX 5, col. 1, ll. 47–53 (emphasis added). After setting up this "need" for improving on prior art quinolone ophthalmics, the patent states that the "invention" addresses that "need" by formulating a *new class* of antibiotics as topical ophthalmics. This distinction between the prior art quinolone class and the "new class" described as the "invention" reveals that the "new class" of drugs to be formulated must not be members of the prior art, quinolone, class of antibiotics. Perhaps even more tellingly, the '830 patent never refers to "moxifloxacin" as a quinolone.

Alcon (AB, pp. 6–7 and 12–13) further argues that what the '830 patent defines as "moxifloxacin" (structure (S)) is erroneous because the structure does not fall within the scope of general structure (I) shown in column 2. The patent, however, does not require "moxifloxacin" to be within general formula (I). Indeed, Dr. Taylor admitted that the patent does not explicitly state that "moxifloxacin" is the most preferred *of the compounds within general formula (I)*. Tr.

130:5–13. He further conceded that structure (S) cannot be encompassed within the structure of general formula (I) because general formula (I) lacks information as to where substituent "A" should go, and thus does not provide for the methoxy group at position 8. Tr. 130:14–17. Alcon (AB, p. 13, fn. 7) conveniently responds that the missing substituent "A" in formula (I) is yet another "obvious typographical error" that the Court should now fix for them. However, even Dr. Taylor's testimony shows that the nature of this so-called "obvious" error is not so obvious. While his initial opinion was that the missing "A" could only replace the carbon at position 8 of formula (I) (Tr. 125:10–126:2), Dr. Taylor conceded that it just as easily could replace the nitrogen ("N") at position 2. Tr. 130:20–131:3. Tellingly, Dr. Taylor also testified that such a structure could be an antibiotic (Tr. 131:4–25), yet it would not include moxiflocaxin. Contrary to Alcon's assertions, it does not follow that structure (S) need be within the scope of general structure (I), revealing that Alcon's portrayal of the numerous irregularities in the '830 patent as simple obvious typographical errors is untrue.

C. Teva's Proposed Claim Construction Of "Moxifloxacin" Is Consistent With The Prosecution History of the '830 patent

Alcon further insinuates that Teva's proposed construction fails to take into account the prosecution history of the '830 patent (AB, p. 13). Yet, the prosecution history only further reveals that Alcon sought to distinguish the prior art quinolone class of antibiotics from "moxifloxacin" as defined in the '830 patent.

As filed, the claims of the application which led to the '830 patent were directed to a generic class of compounds having a carboxylic acid or equivalent structure at the 3-position – a feature, as Dr. Taylor testified (Tr. 54:13–55:25), required for a chemical to be a quinolone. PTX 6, BA001-001583 to 85. After the application was rejected by the Patent Office in light of the prior art, however, Alcon amended the claims to recite simply "moxifloxacin," an

amendment supported only by structure (S) from the specification. PTX 6, BA001-002835 to 38. The '830 patent was then allowed without further rejection. PTX 6, BA001-002849.

II. Alcon's Proposed Claim Construction Is Legally And Factually Unsupported

A. Extrinsic Evidence And Expert Testimony Is Not Probative Of The Meaning Of "Moxifloxacin"

Alcon's proposed claim construction is predicated entirely on extrinsic evidence, including the litigation-inspired testimony of its organic medicinal chemistry expert, Dr. Taylor. According to Alcon's theory, a person reading the '830 patent must first (a) somehow know that "moxifloxacin" refers to a chemical having a structure that does not appear in the patent (despite its express attribution of structure (S) to moxifloxacin), and then (b) seek out other literature for guidance as to what the formula actually is. Tr. 122:24–123:7. Alcon provides only a self-serving, circular, presupposition for the first step. As for the second step, Dr. Taylor offers two unrelated extrinsic references—U.S. Patent No. 5,607,942 ("the '942 patent") and an INN dictionary—to change the meaning of the term "moxifloxacin" from the definition provided in the '830 patent. Tr. 120:16–123:7. However, Dr. Taylor concedes, as he must, that the '942 patent provides no guidance whatsoever as to which of its "billions" of compounds should be called "moxifloxacin." Tr. 80:7–14, 120:16–121:8. To rescue his strained interpretation of the patent, he turns to the "Proposed INN List," neither referenced in the patent nor its prosecution history, to resolve which compound he thinks should take the place of the structure (S) disclosed in the '830 patent. Tr. 120:16–123:7; AB, p. 7.

The Federal Circuit has soundly rejected Alcon's approach to claim construction. *Phillips*, 415 F.3d at 1318–19. First, because extrinsic evidence is not a part of the patent, it lacks the virtue of being created contemporaneously with patent prosecution for the purpose of explaining claim term meaning. *Id.* at 18. Second, unlike the patent's specification, the intended

audience of such extrinsic evidence may be different from that of the patent, and therefore the extrinsic evidence "may not reflect the understanding of a skilled artisan in the field of the patent." *Id.* Third, extrinsic evidence, especially expert testimony, is created for the purpose of litigation and therefore may be influenced by bias. *Id.* Fourth, because the universe of potential extrinsic evidence is so broad, there is a danger that litigants will pick and choose the evidence they rely on based on their positions, "leaving the court with the considerable task of filtering the useful extrinsic evidence from the fluff." *Id.* (citation omitted). Fifth, undue reliance on extrinsic evidence such as Alcon's may lessen the weight of the intrinsic evidence, which would undermine the public notice function of patents. *Id.* at 1319. Accordingly, Alcon's extrinsic evidence "is unlikely to result in a reliable interpretation of patent claim scope" because it is divorced from the context of the intrinsic evidence. *Id.*

In short, Alcon's reliance on the testimony of Dr. Taylor (which Alcon calls "unrebutted evidence"[2]) is less reliable than the intrinsic evidence in this case—the express definition in the '830 patent. Thus, for the many reasons noted in *Phillips*, the specification of the '830 patent is a far more reliable guide to the meaning of "moxifloxacin" in the '830 patent than is Dr. Taylor's litigation-inspired, connect-the-dots trek through the two extrinsic references that he selected for purposes of this litigation. The intrinsic evidence dictates that, in the context of the '830 patent, "moxifloxacin" means a compound having the structure (S) that the patent says it has.

The fallacy of Alcon's proposed construction is further revealed by the fact that, if the Court were to construe "moxifloxacin" as used in the '830 patent as Alcon asks, a person reading the patent would have to *ignore* what is expressly stated in the patent. Even Dr. Taylor conceded

[2] Of course, Dr. Taylor's testimony is not really "unrebutted." The fact that he has admitted that the only way a person reading the '830 patent would come to his conclusion would be for that person to ignore the actual disclosure and language of the '830 patent (Tr. 123:4–7) reveals that the patent itself rebuts his opinion as to what the patent discloses.

this to be true. Tr. 122:24-123:7. This flies directly in the face of *Phillips*, an *en banc* decision of the Federal Circuit that forbade ignoring a patent's specification as Alcon now presses. *Phillips*, 415 F.3d at 1315 (mandating considering the specification as the primary source for construing claims). Any claim construction that requires the Court to ignore the patent specification, such as that which Alcon urges here, cannot be the correct one.

B. Dr. Taylor Is Not A Competent Witness To Opine On The Meaning Of "Moxifloxacin" To A Person Of Ordinary Skill In The Art

Alcon devotes much of its brief to the so-called plain and ordinary meaning in September 1998 of moxifloxacin to the person having ordinary skill in the art. AB, pp. 6–15. Alcon's argument is predicated on its assertion that the person having ordinary skill in the art has the qualifications of an "ophthalmologist and/or a microbiologist." However, the bulk of the testimonial evidence cited by Alcon is the testimony of Dr. Taylor, a medicinal chemist who unquestionably lacks the qualifications of a "microbiologist and/or an ophthalmologist." Tr. 45:24–51:8; 99:2–100:1. Since Dr. Taylor admittedly is not a person having ordinary skill in the art relevant to the '830 patent, his testimony should be given little, if any, weight.[3] *See Merck & Co. v. Teva Pharm. USA, Inc.*, 347 F.3d 1367, 1371–1372 (Fed. Cir. 2003) (discounting an expert's testimony as to how a person of ordinary skill in the art would read the patent where the expert was a chemist who was not qualified in pharmacology, the field of the invention); *Forest Labs., Inc. v. Ivax Pharm., Inc.*, 438 F. Supp. 2d 479, 489 (D. Del. 2006), *aff'd*, 501 F.3d 1263 (Fed. Cir. 2007) (expert testimony is "of limited value" when the expert is not qualified to speak from the perspective of a person having ordinary skill in the art).

[3] Indeed, for the reasons explained in Teva's concurrently-filed brief on the invalidity of the '830 patent, the testimony of Alcon's other expert, notably Dr. Zhanel, is similarly not entitled to weight since he, too, not being an ophthamologist, is not fully qualified to speak from the perspective of the "person" of ordinary skill in the art as Alcon has defined that "person."

C. The '830 Patent's Reference To U.S. Patent No. 5,607,942 Is An Improper Attempt At Incorporation By Reference

Alcon (AB, pp. 12–13) argues that the '830 patent's reference to the '942 patent should be used to change the '830 patent's definition of "moxifloxacin." Reliance on information outside the disclosure of the '830 patent, and not properly incorporated by reference, is improper.

"To incorporate material by reference, the host document [here, the '830 patent] must identify with *detailed particularity* what *specific* material it incorporates and ***clearly indicate*** *where* that material is found in the various documents." *Zenon Envtl., Inc. v. U.S. Filter Corp.*, 506 F.3d 1370, 1378 (Fed. Cir. 2007) (quoting *Cook Biotech Inc. v. Acell, Inc.*, 460 F.3d 1365, 1376 (Fed. Cir. 2006) (first emphasis supplied). After providing the structure for "moxifloxacin," the '830 patent states: "Further details regarding the structure, preparation, and physical properties of Moxifloxacin and other compounds of formula (I) are provided in U.S. Patent No. 5,607,942." PTX 5, col. 3, ll. 49–51. This statement, however, fails to indicate in any respect, much less "***clearly indicate***," where in the '942 patent such "further details" are provided.

Indeed, Dr. Taylor conceded that the '942 patent describes "billions" of compounds (Tr. 80:7-14), none of which the '942 patent identifies as "moxifloxacin." Tr. 120:16–121:8. Dr. Taylor also affirmed that at least a third reference, the "Proposed INN List," would be necessary to ascertain the structure that Alcon would have the Court construe as "moxifloxacin." Tr. 120:16–123:7. The '830 patent, thus, does not provide a proper "incorporation by reference" of the '942 patent, and the disclosure of the '942 patent should therefore not be considered as a part of the intrinsic evidence relevant to the construction of "moxifloxacin."

D. Whether "Moxifloxacin" Had An Ordinary Meaning Is Irrelevant

Even if the Court were to find that as of September 1998 "moxifloxacin" had a well-known meaning, this is of no moment. The Federal Circuit in *Honeywell* held that the patentee had redefined a time-honored navigational term (heading), *Honeywell*, 493 F.3d at 1361, which, according to the dissent, had been in use for "centuries." *Id.* at 1367 (Plager, J., dissenting). As in *Honeywell*, Alcon's appeal here to the alleged "well-known" meaning of "moxifloxacin" is legally insufficient to overcome the '830 patent's plain language. *See also Abbott Labs.*, 323 F.3d at 1330 (patentee's explicit redefinition of claim terms controls claim construction, even if terms have "well-known meanings" in the art); *cf. Pfizer Inc. v. Ranbaxy*, 457 F.3d 1284, 1291-92 (Fed. Cir. 2006) (reversing District Court's holding of improperly-dependent claim valid, where District Court based decision, in part, on manner in which one of ordinary skill would read the claim, and instead holding that patentee's error was determinative).

E. Whether The '830 Patent's Definition Leads To A Nonsensical Or Inoperable Claim Is Irrelevant

Alcon seeks to avoid the definition in the '830 patent by positing that structure (S) would not be an antibiotic. AB, p. 10. As a threshold matter, Alcon has no evidence demonstrating that the compound (S) lacks antibiotic activity. Tr. 113:24–114:17. There likewise is no evidence that any one at Alcon has ever studied this compound or tested it even during this litigation. Thus, the premise of Alcon's argument rests entirely on litigation-inspired speculation. Moreover, the '830 patent affirmatively states that "moxifloxacin" *does* have antibacterial properties, as the patent provides MIC data for "moxifloxacin" at col. 3, l. 57 to col. 4, l. 15.

In any event, even if compound (S) were to lack antibiotic activity as Alcon presupposes, Alcon's argument is immaterial to the proper construction of the claim. It is well established that even "a nonsensical result" should not lead a Court to ignore an explicit definition. *Chef*

America, 358 F.3d at 1374. The patent in *Chef America* was directed to a method of producing dough through baking or microwaving, and the claim at issue required "heating the resulting batter-coated dough *to* a temperature in the range of about 400° F to 850° F." *Id.* at 1372 (emphasis added). Heating the dough *to* such an internal temperature would result in burning the dough to a crisp. *Id.* at 1373. Instead of seeking correction under § 255, the patentee asked the Federal Circuit to construe the claim to avoid this inoperable method, in favor of what two of the patent's examples showed; namely, to require heating the dough *at* an oven temperature of about 400° F to 850° F, not heating the dough *to* such a temperature. *Id.* at 1375.

The Federal Circuit rejected the use of claim construction to correct this nonsensical claim, stating that the argument for doing so was "but a restatement of [the patentee's] basic contention that unless we rewrite the claim, the patented process cannot perform its intended function." *Id.* *Chef America* compels a claim construction embracing the '830 patent's definition regardless of whether the compound (S) might or might not function as an antibiotic.

F. Alcon Asks The Court To Improperly Construe The Claim In Light Of Teva's Accused Product In Order To Find Infringement

Alcon's proposed construction also is incorrect because Alcon has asked the Court to construe the term "moxifloxacin" in light of Teva's product. Alcon's request is unjustifiable, as it is improper to "prejudge the ultimate infringement analysis by construing claims with an aim to include or exclude an accused product or process...." *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1326–27 (Fed. Cir. 2006); *see also Exigent Tech., Inc. v. Atrana Solutions, Inc.*, 442 F.3d 1301, 1309 n.10 (Fed. Cir. 2006).

Due to the myriad "errors" in the chemical structures disclosed in the '830 patent, none of them includes the compound Alcon now calls "moxifloxacin." Alcon asks the Court to correct these supposed errors, relying on Dr. Taylor's testimony to show how the corrections should be

made to "cover" the compound included in Teva's proposed product. However, Dr. Taylor's testimony and his purported corrections are not reliable. Notably, Dr. Taylor conceded on cross-examination that these many alleged "errors" could be "corrected" in various ways (Tr. 126:16–24, 129:12–21, 130:20–132:16), yet Dr. Taylor selectively advocates only one of these many possible "corrections," the one that covers Teva's proposed product. The fallacy of Dr. Taylor's approach is manifest from his testimony regarding the structure defined as "moxifloxacin" in the '830 patent. He was asked: "you do understand that Teva's proposed ophthalmic formulation does not include chemical – a chemical that has the structure, don't you?" to which he answered: "Yes, I do. ***It doesn't need to***." Tr. 105:9–18. It "doesn't need to" because Alcon's proposed construction is not only divorced from the context of the '830 patent but plainly is also inspired by Teva's proposed product.

G. Alcon's Proposed Claim Construction Would Frustrate The Public Policy Underlying The Notice Function Of Patents

It has long been a vein of U.S. patent law that people should be able to ascertain from patents' disclosures whether they might infringe them or not. "Fair notice to the public, and to competitors, of what is claimed depends on [courts] holding patentees to what they claim, not to what they might have claimed." *Honeywell,* 493 F.3d at 1368 (Plager, J., dissenting); *see also Ortho-McNeil Pharms., Inc. v. Mylan Labs., Inc.*, 520 F.3d at 1362; *Chef America*, 358 F.3d at 1374. "When courts fail to enforce that responsibility in a meaningful way they inevitably contribute an additional element of indeterminacy to the system." *Honeywell*, 493 F.3d at 1368 (Plager, J., dissenting) ("Sometimes being kind to a party results in being unkind to the larger interests of the society.") ; *cf. Pfizer*, 457 F.3d at 1292 (requiring strict compliance with patent drafting requirements does not "exalt form over substance").

Alcon's proposed construction would vitiate this reasonable policy, and it should not be adopted. *See, e.g., Phillips*, 415 F.3d at 1319 (undue reliance on extrinsic evidence in derogation of patent specification risks undermining the public notice function of patents). It would be manifestly unfair for a member of the public to risk infringement liability and to find out only through extensive litigation that (s)he should have ignored the '830 patent's disclosure and instead dug out some document called the "Proposed INN List," a document referenced nowhere in the '830 patent or its prosecution history, to learn that moxifloxacin has a meaning exotic to the patent itself. Yet, this unjust result is exactly what Alcon urges. The well-reasoned analysis is that the definition Alcon placed in its patent (structure (S)) a decade before this litigation ensued is the proper one.

III. The Product Described In Teva's ANDA No. 78-073 Does Not Contain "Moxifloxacin" As That Term Is Defined In The '830 Patent

Alcon has the burden of proving that the product described in Teva's ANDA infringes claim 1 of the '830 patent. *See, e.g., Centricut, LLC v. Esab Group, Inc.*, 390 F.3d 1361, 1367 (Fed. Cir. 2004). It is undisputed that Teva's ANDA product does not contain any chemical having the structure (S) defined as that of "moxifloxacin" in the '830 patent. See Tr. 105:9–105:18; 105:22–106:1. Rather, the active ingredient in Teva's ANDA product (i) has a carboxylic acid group, not a methyl group, at the 3-position[4] (Tr. 118:15–119:1 (the line at the 3-position of structure (S) is "the classic way for the organic chemist to indicate what is intended to be [methyl] or CH_3")), and (ii) is an S,S enantiomer, not a racemate as shown for compound (S) in the '830 patent **REDACTED** PTX 13, **REDACTED**, 1244:25–1245:5). Teva's ANDA thus does not infringe claim 1 of the '830 patent.

[4] "3-position" in this context refers to the position on the chemical's core double-ring structure, as explained in Alcon's opening brief at pages 2 and 3.

IV. Alcon Is Attempting An Improper End-Run Around 35 U.S.C. § 255

Alcon acknowledges (AB, p. 10) that the '830 patent contains a typographical error with respect to the disclosure of "moxifloxacin." Alcon's proposed claim construction is essentially a request for a correction of the '830 patent. Alcon, though, has decided not to follow the statute, 35 U.S.C. § 255, for seeking correction of "clerical or typographical" errors in patents. Indeed, although Alcon (AB, p. 14, n. 8) makes passing reference to the Court's power to correct patents, a reference to the legal *standard* for the proper exercise of that power is conspicuous in its absence—and understandably so. Alcon knows it would not be proper for this Court to correct Alcon's patent in order to provide Alcon with the claim scope it now desires.

District courts have only limited authority to correct obvious errors in issued patents, *Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1356 (Fed. Cir. 2003), since "[i]t is the job of the patentee, and not the court, to write patents carefully and consistently." *Chef America,* 358 F.3d at 1373. Thus, "[a] district court can correct a patent only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims." *Novo Indus.*, 350 F.3d at 1357. Here, there is clearly at least a "reasonable debate" as to the proper definition of the term "moxifloxacin," based on the '830 patent's claim language and specification. Also, as explained above, the prosecution history does not suggest a different interpretation of the claim than is provided in the specification. Accordingly, even if Alcon had sought correction of its patent under Section 255, correction would be improper here.

V. Alcon's Continued Assertion Of Claim 1 Makes This An Exceptional Case

Under 35 U.S.C. § 285, "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." *See Brasselar, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001) ("unjustified, and otherwise bad faith litigation" is an exceptional case);

see also Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1355 (Fed. Cir. 2005). Clear and convincing evidence is required to support a finding that a case is "exceptional." *See, e.g., Brasselar*, 267 F.3d at 1378-1379. "[B]ad faith litigation, where a patentee initiates litigation on a patent he knows is invalid or not infringed, is conduct offensive to public policy, and can provide a basis for granting attorney fees." *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1372 (Fed. Cir. 2003) (internal citation omitted).

It is clear that Alcon's proposed claim construction is not based on sound legal principles, but is rather an attempt to persuade the Court to correct what Alcon tries to pass off as a "typo". Tr. 21:10-22:4. Alcon has known of these "errors" since mid-2007, at the latest, when Dr. Taylor's expert reports were prepared. Tr. 146:19–147:25. Alcon has thus known for some time that the '830 patent, as issued, does not cover the product described in Teva's ANDA. Despite this knowledge, and instead of seeking correction as prescribed by statute, though, Alcon continued to assert this patent against Teva. Had Alcon pursued correction of the '830 patent under 35 U.S.C. § 255, much discovery, trial, and post-trial briefing would have been avoided.

By attempting its end-run around Section 255, Alcon unjustifiably continued this case and forced Teva to defend itself from an unreasonable charge of infringement. Because of this, the case is "exceptional," and Teva should be awarded its attorneys fees for the expense related to defending itself against Alcon's unjustified charge of infringement.

CONCLUSION

For the reasons discussed herein, the claim term "moxifloxacin" must be defined as the chemical having the structure (S) set forth at column 3, lines 36 to 48 of the '830 patent. Teva's ANDA product does not contain a chemical having that particular structure. Accordingly, the Court should hold that Teva's topical ophthalmic composition described in its ANDA does not infringe claim 1 of the '830 patent, and award Teva attorneys' fees under 35 U.S.C. § 285.

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BAYARD, P.A.

/s/ Richard D. Kirk (rk0922)
Richard D. Kirk (#0922)
Ashley B. Stitzer (#3891)
222 Delaware Avenue, Suite 900
P.O. Box 25130
Wilmington, DE 19899-5130
rkirk@bayardfirm.com
astitzer@bayardfirm.com
(302) 655-5000
Counsel for Defendant,
TEVA PHARMACEUTICALS USA, INC.

OF COUNSEL:

Bruce M. Gagala
M. Daniel Hefner
Douglas A. Robinson
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
Chicago, Illinois 60601

CERTIFICATE OF SERVICE

The undersigned counsel further certifies that, on May 22, 2008, copies of the foregoing document were sent to the following in the manner shown:

BY EMAIL AND BY HAND

Frederick L. Cottrell III, Esquire
Jeffrey L. Moyer, Esquire
Anne Shea Gaza, Esquire
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, Delaware 19801

BY EMAIL AND
BY OVERNIGHT COURIER

Bruce R. Genderson, Esquire
Adam L. Perlman, Esquire
Dov P. Grossman, Esquire
David I. Berl, Esquire
Aaron P. Maurer, Esquire
Williams and Connolly
725 Twelfth Street, N.W.
Washington, D.C. 20005

/s/ Richard D. Kirk (rk0922)
Richard D. Kirk